(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property **Organization** International Bureau





(43) International Publication Date 23 September 2004 (23.09.2004)

PCT

(10) International Publication Number WO 2004/080419 A3

- (51) International Patent Classification⁷: A61K 39/395, 39/40, 39/42, C07K 16/00
- (21) International Application Number:

PCT/US2004/007503

- (22) International Filing Date: 12 March 2004 (12.03.2004)
- (25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data: 10/388,389

12 March 2003 (12.03.2003)

- (71) Applicants (for all designated States except US): NEU-RALAB LIMITED; 102 St. James Court, Flatts Smith FL04 (BM). WYETH [US/US]; Five Giralda Farms, Madison, NJ 07940 (US).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): BASI, Guriq [US/US]; 514 Rhodes Drive, Palo Alto, CA 94303 (US). SALDANHA, Jose, W. [GB/GB]; 21 Fillebrook Avenue, Enfield EN1 3BD (GB). YEDNOCK, Ted [US/US]; 184 Arroyo Road, P.O. Box 831, Forest Knolls, CA 94933 (US).
- (74) Agents: MANDRAGOURAS, Amy, E. et al.; Lahive & Cockfield, LLP, 28 State Street, Boston, MA 02109 (US).

- (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM. TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.
- (84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

- with international search report
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments
- (88) Date of publication of the international search report: 6 May 2005

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: HUMANIZED ANTIBODIES THAT RECOGNIZE BETA AMYLOID PEPTIDE

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US04/07503

A. CLASSIFICATION OF SUBJECT MATTER					
IPC(7) : A61K 39/395, 39/40, 39/42; C07K 16/00 US CL : 424/130.1, 141.1, 142.1; 530/387.1, 387.3, 388.1, 388.15					
According to International Patent Classification (IPC) or to both national classification and IPC					
B. FIELDS SEARCHED .					
Minimum documentation searched (classification system followed by classification symbols)					
U.S.: 424/130.1, 141.1, 142.1; 530/387.1, 387.3, 388.1, 388.15					
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched					
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)					
Please See Continuation Sheet					
C. DOCUMENTS CONSIDERED TO BE RELEVANT					
Category *	Citation of document, with indication, where	appropriate,	, of the relevant passages	Relevant to claim No.	
A	US 2004/0043418 A1 (HOLTZMAN ET AL.) 04	March 2004	4 (04.03.2004), entire	1-62 and 79-81	
	document.				
A	US 2004/0241164 A1 (BALES ET AL.) 02 December 2004 (02.12.2004), entire 1-62 and 79-6 document.			1-62 and 79-81	
A	US 2004/0265919 A1 (VANDERSTICHLELE ET AL.) 30 December 2004 (30. 12.2004), 1-62 and 79-81			1-62 and 79-81	
	entire document.				
A	VANDERSTICHELE, H. ET AL. Standardization of Measurement of b-amyloid(1-42) in 1-62 and 79-81 Cerebrospinal Fluid and Plasma. Amyloid: Int. J. Exp. Clin. Invest. December 2000,				
	Vol. 7, No. 4, pages 245-258, entire document.	Exp. Cili.	invest. December 2000,		
A	,			1-62 and 79-81	
	Amyloid-b In Vivo by Immunotherapy. The Journal of Neuroscience. 15 September 2002, Vol. 22, No. 18, pages 7873-7878, entire document.				
•	voi. 22, 140. 18, pages 1813-1818, entire documen	11.			
Further	documents are listed in the continuation of Box C.		See patent family annex.		
	pecial categories of cited documents:	"T"	later document published after the inter-	national filing date or priority	
"A" document	defining the general state of the art which is not considered to be		date and not in conflict with the applica principle or theory un derlying the inven		
	ar relevance	#3/#			
"B" earlier ap	olication or patent published on or after the international filing date	"X"	document of particular relevance; the c considered novel or cannot be considered		
	document which may throw doubts on priority claim(s) or which is cited to		when the document is taken alone		
establish the publication date of another citation or other special reason (as specified)		"Y" document of particular relevance; the considered to involve an inventive step			
	ent referring to an oral disclosure, use, exhibition or other means		combined with one or more other such being obvious to a person skilled in the	documents, such combination	
"P" document published prior to the international filing date but later than the priority date claimed		"&"	document member of the same patent fa	ımıty	
Date of the actual completion of the international search		Date of m	Date of mailing of the international search report		
		09 MAR 2005			
15 February 2005 (15.02.2005) Name and mailing address of the ISA/US		Authorized officer			
Mail Stop PCT, Attn: ISA/US		N. Kovins go			
Commissioner for Patents P.O. Box 1450		Christopher J Nichols, Ph. D.			
Alexandria, Virginia 223 13-1450			e No. (571) 272- 1600		
racsimile No	Facsimile No. (703) 305-3230				

INTERNATIONAL SEARCH REPORT

International application No. PCT/US04/07503

BOX III. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group 1, claim(s) 1-62 and 79-81, drawn to the 3D6 antibody, a method of preventing or treating an amyloidogenic disease in a patient comprising using the 3D6 antibody, and pharmaceutical compositions comprising same and a method of producing the 3D6 antibody or fragment thereof.

Group 2, claim(s) 63-71 and 138-141, drawn to an isolated polypeptide comprising SEQ ID NO: 2 and 4, variants comprising same.

Group 3, claim(s) 72-78, drawn to an isolated nucleic acid encoding the 3D6 antibody, vectors, and host cell comprising same.

Group 4, claim(s) 82-83 and 157-158, drawn to a method for identifying residues amenable to substitution in a humanized immunoglobulin variable framework region.

Group 5, claim(s) 84-137 and 154-156, drawn to the 10D5 antibody, a method of preventing or treating an amyloidogenic disease in a patient comprising using the 10D5 antibody, and pharmaceutical compositions comprising same and a method of producing the 10D5 antibody or fragment thereof.

Group 6, claim(s) 142-146, drawn to an isolated polypeptide comprising SEQ ID NO: 14 and 16, variants comprising same.

Group 7, claim(s) 147-153, drawn to an isolated nucleic acid encoding the 10D5 antibody, vectors, and host cell comprising same.

The inventions listed as Groups 1-9 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Group 1 is drawn to the special technical feature of 3D6 antibody, a method of preventing or treating an amyloidogenic disease in a patient comprising using the 3D6 antibody, and pharmaceutical compositions comprising same, which is not required by any of the other groups.

Group 2 is drawn to the special technical feature of an isolated polypeptide comprising SEQ ID NO: 2 and 4, variants comprising same, which is not required by any of the other groups.

Group 3 is drawn to the special technical feature of an isolated nucleic acid encoding the 3D6 antibody, vectors, and host cell comprising same, which is not required by any of the other groups.

Group 4 is drawn to the special technical feature of a method for identifying residues amenable to substitution in a humanized immunoglobulin variable framework region, which is not required by any of the other groups.

Form PCT/ISA/210 (extra sheet) (January 2004)